In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-1122V
Filed: March 29, 2023

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REBECCA HOFFMAN, *as administrator of the* ESTATE OF KAREN CHRISTNER,	*	To Be Published
Petitioner,	*	
v.	*	Decision on Attorneys' Fees and Costs; Reasonable Basis; Influenza ("flu") Vaccine; Transverse Myelitis ("TM").
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
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Braden Blumenstiel, Esq., The Law Office of DuPont & Blumenstiel, Dublin, OH, for petitioner.
Darryl Wishard, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

DECISION ON ATTORNEYS' FEES AND COSTS[1]

On September 12, 2016, Karen L. Christner ("Ms. Christner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*[2] ("Vaccine Act" or "Program").[3] Ms. Christner alleged that she received an influenza vaccine on September 13, 2013, and thereafter suffered from "pain, weakness, and limitations in her legs," and paraplegia. Petition at ¶¶ 4, 5. The matter was dismissed for insufficient proof on March 26, 2020. ECF No. 91.

On December 18, 2020, petitioner filed an untimely Motion for Attorneys' Fees and Costs. ECF No. 95. As more specifically set forth in the procedural history below, respondent filed his

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[1] This Decision will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet.** As provided in 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this Decision will be available to the public in its present form. *Id.*
[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).
[3] On November 12, 2019, Rebecca Hoffman ("Ms. Hoffman" or "petitioner"), as administrator of the estate of Karen Christner, was substituted in as the petitioner in this matter. ECF No. 82.

response in opposition to petitioner's Motion on January 26, 2021, arguing that petitioner failed to establish a reasonable basis for her claim and therefore is not entitled to an award of fees and costs. ECF No. 101 at 1.

I. Procedural History

The petition was filed by petitioner's then-counsel, James Blumenstiel, on September 12, 2016, with petitioner's first affidavit annexed thereto. Petition, ECF No. 1. Petitioner filed medical records on November 2, 2016. Petitioner's Exhibits ("Pet. Ex") Pet. Ex. 1-5, ECF No. 7.

An initial status conference was held on December 8, 2016, at which time inconsistencies regarding onset between the contemporaneous medical records and petitioner's affidavit were discussed. Respondent advised that, having reviewed the records, he intended to defend the case. Petitioner's counsel advised that petitioner contacted him on the eve of the statute of limitations and the petition was filed without a thorough review of the medical records, which were still being received. Petitioner was ordered to file a status report indicating how she intended to proceed in 90 days. Respondent's Rule 4(c) Report deadline was suspended. ECF No. 9.

Petitioner filed additional medical records on December 19, 2016; March 3, 2017; March 9, 2017; and May 18, 2017. *See* Pet. Ex. 6-7, ECF No. 10; Pet. Ex. 9-13G, ECF No. 15; Pet. Ex. 13-19, ECF No. 19; Pet. Ex. 20, ECF No. 28. Petitioner filed a supplemental affidavit on January 6, 2017.[4] Pet. Ex. 8, ECF No. 14.

On March 8, 2017, petitioner filed a status report advising that she planned to file an expert report in support of her claim. ECF No. 17. An Order issued on March 8, 2017, scheduling the filing of an expert report by May 8, 2017. Petitioner failed to comply with the court-ordered deadline. On May 9, 2017, my law clerk emailed petitioner's counsel regarding the missed deadline. Petitioner's counsel responded via email, advising that he had not yet secured an expert and would file a Motion for Extension of Time on May 10, 2017. On May 10, 2017, petitioner's counsel filed a "Notice of Filing Motion for Extension of Time," requesting an additional 60 days to file an expert report. ECF No. 22. According to the Clerk's Office, this document was improperly filed as a "Notice of Filing" instead of a "Motion for Extension of Time." My law clerk emailed petitioner's counsel and informed him that the motion was filed incorrectly and that he needed to file a Motion to Strike and properly file a Motion for extension of time. Petitioner failed to file the Motion to Strike as directed. On May 12, 2017, an Order to Show Cause issued as to why the case should not be dismissed for failure to comply with court-ordered deadlines. ECF No. 24.

On May 16, 2017, petitioner's counsel filed a Motion to Strike the improperly filed Motion. ECF No. 25. Petitioner then properly filed a Motion for Extension of Time within which to file an

[4] Petitioner's first affidavit placed the onset of her symptoms "around Christmas of 2013," but her supplemental affidavit placed onset of her symptoms "…within two months of [her] flu vaccination on September 13, 2013…." *See* Pet. Ex. 5 at ¶12, ECF No. 7; Pet. Ex. 8 at ¶11, ECF No. 14. However, when petitioner presented to the emergency room eight months after her flu vaccine on May 8, 2014, she reported onset of symptoms "that morning." She was diagnosed with TM at that time. She made no mention of any vaccine-related complaints to any medical provider between September 13, 2013 and May 8, 2014 or anytime thereafter, until two of her treating physicians were presented with questions from petitioner's counsel as set forth below. *See* Pet. Ex. 1 at 1-3, ECF No. 7.

expert report and additional medical records. ECF No. 26. On May 17, 2017, petitioner's counsel filed a response to the Order to Show Cause, explaining that he was unable to comply with court-ordered deadlines because he did not have secretarial help. ECF No, 27. Petitioner was ordered to file an expert report by no later than July 17, 2017. On May 18, 2017, petitioner's counsel filed additional medical records and a status report detailing his efforts to learn how to use CM/ECF. Pet. Ex. 20; ECF No. 28, 30-31.

On July 14, 2017, petitioner filed another Motion for Extension of Time until September 1, 2017 to file an expert report. Respondent advised via email that he was not opposed to this extension of time but would oppose future extensions. Petitioner's motion was granted. ECF No. 33, 34

On September 1, 2017, petitioner's counsel filed a status report stating that one of petitioner's treating physicians had agreed to write an "opinion letter" in support of petitioner's claim. ECF No. 35. The undersigned issued an order for petitioner to file an expert report by September 8, 2017, or an Order to Show Cause would be issued. Non-PDF Scheduling Order, issued Sept. 1, 2017. Petitioner failed to file the expert report.

Another Order to Show Cause issued on September 11, 2017. ECF No. 36. On the same date, petitioner filed a status report in response to the Order to Show Cause stating that he intended to file expert reports over the next two weeks. ECF No. 37. Petitioner then filed a formal response to the Order to Show Cause on September 13, 2017. ECF No. 38.

On September 19, 2017, petitioner filed "expert reports" from Dr. Kisanuki (Pet. Ex. 21), Dr. Racke (Pet. Ex. 22), and Dr. Miller (Pet. Ex. 23). ECF Nos. 39-40. These reports were discussed during a status conference held on September 27, 2017. Specifically, petitioner's treating physicians, Drs. Kisanuki and Racke, opined in their respective reports that they could not connect petitioner's vaccine to the onset of her TM eight months later. Pet. Ex. 21; Pet. Ex. 22. The third report, authored by Dr. Miller, an expert in rheumatology hired by petitioner, accepted as true the facts contained in petitioner's affidavits, although they were drafted several years after the events and contained a timeline of events that was unsupported by the contemporaneous medical records. Pet. Ex. 23. Dr. Miller wrote that HIPAA laws require petitioner's affidavit be accepted as part of the medical record and as accurate and true, and therefore, there was a causal relationship between the vaccine and onset of TM based on the facts contained in the affidavits. *Id*. at 2-3. Counsel was advised that Dr. Miller is not the finder of fact in this case and this Court is not bound by any "laws" requiring it to accept as true statements made by a petitioner, particularly where those statements conflict with the contemporaneous medical records. Scheduling Order at 1, ECF No. 42. Respondent requested a deadline be set for his Rule 4 (c) Report. The deadline was set for November 27, 2017. *Id*. An onset hearing was discussed, and the parties were directed to confer and choose a hearing date via joint status report by December 27, 2017. *Id.* That joint status report was never filed.

Instead, petitioner filed a Statement of Completion on September 29, 2017 and a "First Motion for Hearing on Entitlement", requesting that a hearing date be assigned sooner than the next available August 2018 date as discussed during the status conference, because she had no husband or children to assist in her care. Petitioner requested that a "Staff Attorney or Magistrate"

conduct the hearing in the event the Court's calendar did not permit for an earlier hearing date. ECF No. 43, 44.

My law clerk emailed petitioner's counsel advising that only a fact hearing regarding onset had been discussed at the status conference, not an entitlement hearing. In response to the email, petitioner filed a status report referencing her moving papers and arguing that onset and entitlement should be heard in one hearing to avoid further delay. ECF No. 45. A status conference was set for November 20, 2017.

Respondent filed his Rule 4(c) Report ("Resp. Rpt.") on October 4, 2017, advising that petitioner had presented insufficient evidence to meet the *Althen* criteria and petitioner's claim lacked a reasonable basis. Resp. Rpt. at 13, ECF No. 46. Respondent filed a journal article (Resp. Ex. A); a short biography of petitioner's expert, Dr. Miller and a list of his publications from the Northwestern website (Resp. Ex. B); an article on the symptoms and causes of transverse myelitis from the Mayo Clinic website (Resp. Ex. C); a short biography of petitioner's treater, Dr. Racke from The Ohio State University website (Resp. Ex. D); a PubMed generated list of publications by Dr. Racke (Resp. Ex. E); and a short biography of petitioner's treater, Dr. Kisanuki from The Ohio State University website (Resp. Ex. F). ECF No. 46.

A consented Motion for substitution of counsel was filed on November 6, 2017, substituting Braden Blumenstiel as attorney of record in place of James Blumenstiel, his father. ECF No. 47. The Motion was accompanied by an affidavit of petitioner affirming that James Blumenstiel had been practicing law with his son, Braden Blumenstiel, for the past 13 years and that Braden Blumenstiel had "focused a portion of his practice of law on representing those rare individuals who suffered adverse reactions to a vaccine." Petitioner therefore approved of the substitution of attorney. *Id*.

A status conference was held on November 20, 2017 during which a detailed discussion about this case was had for the benefit of Braden Blumenstiel. Scheduling Order, issued Nov. 20, 2017; ECF No. 48. It was noted that respondent filed his Rule 4(c) Report on October 4, 2017, in which he raised reasonable basis as of September 19, 2017. ECF No. 46. Petitioner's contemporaneous medical records were discussed, particularly her receipt of an influenza vaccine on September 13, 2013, her presentation to the emergency room eight months later on May 8, 2014 with an abrupt onset of weakness and burning in her hips and knees, and her report to the ER physicians that her symptoms began that morning. Pet. Ex. 4 at 51; Pet. Ex. 1 at 1-3. Petitioner's first affidavit was also discussed in which petitioner affirmed that following her September 13, 2013 flu vaccine and "sometime over the next couple of months I began to recognize unusual symptoms" and "in the winter months, perhaps December, I began to experience a real weakness in both my legs…" Pet. Ex. 5 at 1. It was discussed that even if one were to accept the timing as presented by petitioner in her affidavit prepared several years after the events, a three-month onset is not supported by the relevant medical literature for TM. *See Farley v. Sec'y of Health & Human Servs*., No. 13-683V, 2015 WL 5031989 (Fed. Cl. Spec. Mstr. July 31, 2015) (finding that the onset of transverse myelitis three or more months following an influenza vaccine was not within a "medically appropriate time frame").

Further, the "opinion letters" from petitioner's treating physicians Dr. Racke and Dr. Kisanuki were discussed. Neither of petitioner's treaters could connect petitioner's receipt of the influenza vaccine to her onset of TM. *See* Pet. Ex. 21, 22. As an experienced attorney in the program, counsel surely knew that the view of treating physicians is probative with respect to causation. *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1326 (Fed. Cir. 2006) ("…medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'") (internal citations omitted). It was noted that in addition to being a neurologist, Dr. Racke is a neuroimmunologist who specializes in the study of multiple sclerosis, transverse myelitis, other demyelinating disorders, and cytokine regulation, placing him in a unique position to opine on petitioner's alleged injury. *See* Pet. Ex. 22. Further discussed was Dr. Miller's report and his reliance on the facts contained in petitioner's affidavit rather than the contemporaneous medical records. Dr. Miller opined that HIPAA permits a patient to change their records, and in so doing, Dr. Miller concluded petitioner's injuries were causally related to her influenza vaccine. *See* Pet. Ex. 23. It was noted that Dr. Miller's report did not meet the *Althen* criteria. Petitioner was ordered to file a status report in thirty days advising how petitioner wanted to proceed. Scheduling Order, issued Nov. 20, 2017; ECF No. 48.

On November 28, 2017, petitioner filed a Motion for Interim Attorneys' Fees and Costs. Motion for Interim Fees, ECF No. 49. Respondent filed an unopposed Motion for extension of time to respond, which was granted. ECF No. 50. Respondent filed his response in opposition to the Motion for Interim Attorneys' Fees and Costs on January 11, 2018. ECF No. 53. Petitioner filed an untimely reply on January 22, 2018, advising he could wait until the end of the case. ECF No. 54. A decision was issued on January 24, 2018, denying petitioner's Motion for Interim Attorneys' Fees and Costs. ECF No. 55.

On December 20, 2017, petitioner filed a status report and a Motion for extension of time until January 5, 2018 to advise how she intended to proceed. ECF No. 51. The request was granted. Non-PDF Order, issued Dec. 20, 2017.

On January 8, 2018, three days after the deadline set in the Order, petitioner filed an untimely status report advising that she would like to confer with an expert and participate in an onset hearing wherein petitioner could testify "regarding the onset of her symptoms and the impact they have had on her activities of daily life." ECF No. 52.

A status conference was held on February 20, 2018, during which I explained that, while I was sympathetic to petitioner's condition and appreciated the limitations with which petitioner was living, it was unlikely that an onset hearing would benefit petitioner as it may result in further inconsistencies in petitioner's representation of the onset of her symptoms. Additionally, any testimony from petitioner regarding the impact of her TM on her daily life would be proof of damages, not onset or entitlement. Scheduling Order at 1-2, ECF No. 57. Based on the record, different ways to exit the Vaccine Program were discussed. Petitioner's counsel requested time to confer with his client and determine the appropriate avenue for dismissal of petitioner's claim. *Id*. at 2. A joint status report was to be filed on March 26, 2018. *Id.*

Rather than the joint status report ordered, petitioner filed a status report on March 26, 2018, requesting that respondent file a Motion to Dismiss so that she would have the opportunity to respond to respondent's argument's regarding her claim. ECF No. 60.

On March 27, 2018, respondent filed a Motion for Summary Judgment. ECF No. 61. Petitioner filed a response on April 10, 2018. ECF No. 62. As more specifically detailed in the Order issued on July 25, 2018, I denied respondent's Motion for Summary Judgment because onset was an issue of material fact in dispute. *See* Order at 3, ECF No. 63.

A status conference was held on September 5, 2018, during which petitioner's counsel requested and was granted a final thirty days to file any additional evidence in support of her claim before respondent filed a Motion to Dismiss. ECF No. 65.

On October 4, 2018, petitioner's counsel filed a status report advising that petitioner had passed away several months before and requesting a status conference to discuss how to proceed.[5] ECF No. 66. Respondent filed a Motion to Dismiss on October 5, 2018. ECF No. 67.

A status conference was held on October 12, 2018. During the conference, petitioner's counsel stated that he did not believe that an estate had been opened and was unsure whether petitioner had any surviving relatives. Petitioner's counsel was ordered to file a status report by November 26, 2018, advising of his efforts to locate a relative or friend that had been appointed to handle the late petitioner's affairs. ECF No. 68.

On November 28, 2018, two days after the court-ordered deadline, petitioner's counsel filed a status report describing his attempts to contact the individuals listed in petitioner's obituary. Petitioner's counsel advised that he had been unsuccessful in locating petitioner's next of kin but would continue his efforts. ECF No. 69.

On November 29, 2018, I issued an Order pursuant to Rule 25(a)(1) of the Rules of the Court of Federal Claims ("RCFC") that provides in the event of death when the claim is not extinguished,

> the court may order substitution of the proper party. A motion for substitution may be made by any party or by the decedent's successor or representative. *If the motion is not made within 90 days after service of a statement noting the death, the action by the decedent must be dismissed*" (emphasis added)

ECF No. 70. The Order advised that the 90-day window for substitution of the proper party would end on January 2, 2019, and the Motion to Substitute a representative for petitioner must be filed by that date or the petition would be dismissed pursuant to the Rules.

Petitioner's counsel failed to file a Motion to Substitute a representative for petitioner and failed to communicate with the Court in any way by the January 2, 2019 deadline. Given petitioner's counsel's habitual disregard for court-ordered deadlines, the Decision dismissing the

[5] Petitioner apparently passed away in the summer of 2018. Petitioner's counsel did not mention her death during the September 2018 status conference or otherwise advise when he learned of her death. Status Report, ECF No. 66.

claim pursuant to Rule 25(a)(1) did not issue until January 15, 2019. ECF No. 71. Petitioner's counsel then filed a Motion for Review on February 14, 2019, along with an affidavit of Rebecca Hoffman, who was designated as administrator of petitioner's estate. ECF Nos. 73, 74. The Motion for Review was assigned to the Honorable Victor Wolski on February 14, 2019. ECF No. 75. Respondent filed his response on March 15, 2019. ECF No. 76.

On October 25, 2019, the United States Court of Federal Claims remanded the matter for reconsideration because a representative of petitioner's estate had been identified. The merits of the claim were not addressed. *See* Order at 4, ECF No. 78. On October 28, 2019, petitioner's counsel was ordered to file a Motion substituting Rebecca Hoffman as administrator of the estate by no later than November 12, 2019. ECF No. 79. The Motion was filed on November 12, 2019 and granted the same day, substituting Rebecca Hoffman as the administrator. ECF Nos. 81, 82.

On November 19, 2019, a detailed Order was issued outlining the history of this case for the benefit of Rebecca Hoffman as the administrator of the decedent's estate. The Order directed that it be provided to Ms. Hoffman, who was to file a signed affidavit acknowledging receipt of the Order and confirming that she reviewed the evidence and understood all the facts and events associated with the case by January 17, 2020. Ms. Hoffman was to advise how she intended to proceed. ECF No. 84.

On January 2, 2020, respondent filed his expert report of Jeffrey Cohen, M.D. along with Dr. Cohen's CV and cited literature. ECF Nos. 85, 86.

Petitioner missed the January 17, 2020 deadline and filed a Motion for additional time within which to file her affidavit three days later, on January 21, 2020. A new deadline of February 4, 2020 was set. ECF No. 87. The affidavit was untimely filed on February 5, 2020. Petitioner advised she would be filing a Motion for Dismissal Decision. ECF No. 88. An Order issued for the filing of the Motion for Dismissal Decision by March 9, 2020. Non-PDF Scheduling Order, issued Feb. 6, 2020.

Petitioner failed to comply with the March 9, 2020 deadline. An Order to Show Cause as to why the petition should not be dismissed was issued on March 17, 2020. ECF No. 89. Petitioner filed her Motion for voluntary dismissal pursuant to Rule 21(b) eight days later, on March 25, 2020. ECF No. 90. A Decision was issued dismissing the petition on March 26, 2020. ECF No. 91.

Petitioner's Motion for Attorneys' Fees and Costs was due by October 25, 2020. Petitioner failed to comply with this deadline. *See* Vaccine Rule 13(a).[6] Two months after the deadline, on December 18, 2020, petitioner filed a Motion for an extension of 60 days beyond the 180 days required to file for Attorneys' Fees and Costs, submitting that due to Covid, the State of Ohio issued a stay-at-home order in March 2020 that led to most state-related case deadlines being stayed until July 2020. Petitioner submitted that although counsel and staff were working remotely from March to June 2020, there was a significant increase in activity in counsel's state-related

[6] Vaccine Rule 13(a) requires that "[a]ny request for attorney's fees and costs pursuant to 42 U.S.C. § 300aa-15(e) must be filed no later than 180 days after the entry of judgment of the filing of an order concluding proceedings under Vaccine Rule 10(d)(3) or 29." Judgment entered in this matter on April 28, 2020. ECF No. 92.

cases when the stay order ceased. Petitioner's counsel claimed that when work began on the Motion for Attorneys' Fees and Costs in June 2020, "counsel for petitioner concluded it would be beneficial to conduct additional discovery on the issues of what constituted 'good faith' and 'reasonable basis' under the Vaccine Act…It is hoped the additional research conducted will benefit this Court and all petitioners counsel represents.[7] Unfortunately, due to a variety of factors, the motion for fees and expenses was inadvertently not filed by the deadline in this case." ECF No. 94. Petitioner then filed her Motion for Attorneys' Fees and Costs on that same day. Motion for Fees, ECF No. 95. On December 29, 2020, respondent filed a Motion for extension of time within which to file his response to petitioner's Motion for extension of time and requested that the deadline to respond to the Motion for Attorneys' Fees and Costs be deferred until after a ruling on petitioner's Motion for extension of time. ECF No. 96. Respondent's Motion was granted. ECF No. 97.

On January 4, 2021, respondent filed his response opposing petitioner's Motion to extend the deadline for her Motion for Attorneys' Fees and Costs. ECF No. 98. Petitioner filed a reply on January 11, 2011. ECF No. 99. I issued an Order on January 15, 2020, granting petitioner's Motion for an extension of the 180-day period within which to file for attorneys' fees and costs. As more specifically contained therein, petitioner's counsel's repeated failure to comply with court-ordered deadlines in this and other vaccine cases in which he is involved was documented, along with the arguments made by respondent's counsel.[8] Predecessor counsel had a similar disregard for deadlines.[9] This habitual dilatory attitude toward deadlines was particularly egregious given the Federal Circuit's caution to both predecessor and current counsel that counsel "had an obligation to monitor the docket." *Moczek v. Sec'y of Health & Human Servs*., 776 Fed. App'x 671, 674 n.3 (2019). However, due to the unique circumstances Covid presented, and even though the Court of Federal Claims and all other practitioners in the program continued in the normal course of business throughout the pandemic without missing deadlines, I granted the Motion and extended the deadline to file the Motion for Attorneys' Fees and Costs despite its delinquency. ECF No. 100.

Respondent filed his response to the Motion for Fees and Costs on January 26, 2021, maintaining his position that petitioner lacked a reasonable basis for her claim and was not entitled

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[7] Despite this representation, petitioner never mentions *Simmons* or *Cottingham*, both of which had been decided at the time she filed her moving papers.

[8] *See, e.g.*, ECF No. 52 (Petitioner's status report filed Jan. 8, 2019, three days out of time); ECF No. 59 (Order *sua sponte* extending the deadline for petitioner's joint status report from Mar. 23, 2018 to Mar. 26, 2018, following a missed the Mar. 23, 2018 deadline); ECF No. 69 (Petitioner's status report filed Nov. 28, 2018, two days out of time); ECF No. 71 (Decision issued Jan. 15, 2019, after petitioner failed to respond to the Court's previous Order setting a deadline of Jan. 2, 2019); ECF No. 87 (Motion for Extension of Time filed Jan. 21, 2020, four days out of time); ECF No. 89 (Order to Show Cause issued Mar. 17, 2020, for petitioner's failure to respond to the Court's previous Order setting a deadline of Mar. 9, 2020); *see also Dia v. Sec'y of Health & Human Servs*., No. 14-954, 2017 WL 2644695, at *1 (Fed. Cl. Spec. Mstr. May 25, 2017) (the special master noted that Mr. Blumenstiel missed "various deadlines without filing an appropriate motion for enlargement of time"), *Duncan v. Sec'y of Health & Human Servs.*, No. 16-1367V, 2020 WL 6738118 (Fed. Cl. Spec. Mstr. Oct. 19, 2020), mot. for review denied, *Duncan v. Sec'y of Health & Human Servs*., No. 16-1367V, 2021 WL 1748217 (Fed. Cl. Apr. 19, 2021) (noting Mr. Blumenstiel's missed deadline and many motions for extension of time).

[9] *See, e.g.*, ECF No. 24 (Order to Show Cause issued May 12, 2017, after petitioner failed to respond to the Court's previous Order setting a deadline of May 8, 2017); ECF No. 36 (Order to Show Cause issued Sept. 11, 2017, after petitioner failed to respond to the Court's previous Order setting a deadline of Sept. 8, 2017).

to an award of fees and costs. Response, ECF No. 101. Petitioner filed a reply on February 2, 2021. Reply, ECF No. 102.

This matter is ripe for adjudication.

II. Factual Background[10]

A. Summary of Relevant Medical Records

The decedent had an extensive medical history which included ductal carcinoma in situ (breast cancer), vitamin D deficiency, hypothyroidism, and osteoporosis. She was status post right partial mastectomy/lumpectomy, tumor excision of her finger, multiple vascular tumor excisions, and tonsillectomy. Pet. Ex. 1 at 10.

On February 27, 2013, petitioner had a follow up visit for a history of breast cancer with partial mastectomy and sentinel lymph node biopsy for ductal carcinoma in situ taken February 22, 2012. Hormone receptors were positive. She had a full course of radiation and was taking an aromatase inhibitor. She reported achiness. Pet. Ex. 2 at 107.

By March 8, 2013, her radiation treatment was complete. There were no palpable nodes, and a mammogram done on February 27, 2013 was stable. Pet. Ex. 2 at 105, 109; Pet. Ex. 6 at 1.

On July 30, 2013, petitioner was noted to have moderate myope and peripapillary atrophy of both eyes. Pet. Ex. 2 at 110.

The subject flu vaccine was received on September 13, 2013 at a primary care visit. The record reflects a detailed discussion regarding her need for a colonoscopy and a thyroid ultrasound due to possible nodules. Pet. Ex. 4 at 50-52; Pet. Ex. 2 at 128. Her father died at 32 from colon cancer. *Id*.

Petitioner presented to Hobbs Oncology Center ("Hobbs") on September 17, 2013 for breast cancer follow up. Her condition was stable. Pet. Ex. 2 at 112. She underwent ultrasound of the thyroid on September 19, 2013; she had a multinodular goiter. Pet. Ex. 2 at 121; Pet. Ex. 4 at 62. She underwent a colonoscopy on October 8, 2013 with removal of polyps. A letter from her gastroenterologist dated October 14, 2013 noted benign polyps but a tubulovillous adenoma with high grade dysplasia, close to being cancerous. Pet. Ex. 2 at 113, 119; Pet. Ex. 4 at 156. Digital mammography was performed on February 17, 2014 and was stable. Pet. Ex. 3 at 129. Petitioner returned to Hobbs on March 19, 2014. Her colonoscopy results were noted with follow up colonoscopy to be done in October 2014. She had no rectal complaints or bleeding, pelvic pain, or breast masses or pain. Pet. Ex. 3 at 109. A genetic evaluation was discussed, but she chose not to pursue this because she had no children or significant living relatives. *Id*. at 110. Petitioner presented for repeat ultrasound of the thyroid on May 2, 2014. No treatment was prescribed. Pet. Ex. 4 at 61.

[10] Any reference to "petitioner" in this section refers to the original petitioner, Karen L. Christner.

Between September 13, 2013 and May 8, 2014, petitioner did not report any weakness, numbness, pain, paraplegia, or other complaints or changes in her health to any medical professional, either in general or associated with her receipt of the September 13, 2013 flu vaccine.

On May 8, 2014, petitioner presented to the emergency room reporting weakness in her legs. Pet. Ex. 1 at 3. She reported she felt okay when she awoke that morning and went to work. Later that morning, her legs started to feel a bit weak at the hip with a burning sensation. It started to get worse, and she drove herself home around 11:30. At around 1 pm, she felt like she may fall and was shaky so she sat down on the ground but could not get up. *Id*. She had taken Advil to help make her feel better, but she did not feel any better. She denied back pain or loss of bladder or bowel function. She reported being stuck on the floor and trying to move around on her arms to call for help but became too tired. *Id*. Her coworkers called and came to the house when she did not answer the phone and called 911. A head CT on arrival was negative. *Id*. at 8. She reported no recent fevers, injections in her back, or other symptoms; she felt well until that morning. *Id*. at 3. An MRI of the thoracic spine showed abnormal edema at T4-T10, and the differential diagnosis included transverse myelitis vs. vasculopathy with ischemia such as lupus. An MRI of the lumbar spine showed hyperintense T2 signal at T10. *Id.* at 8-9. A metabolic panel was normal. *Id.* at 30. The assessment was acute onset of paraparesis at the thoracic sensory level. The clinical history was suggestive of transverse myelitis[11] and MRI findings included severe cervical canal stenosis with cord compression, but the findings did not fit the clinical picture. Aggressive treatment for myelitis was recommended before considering cervical surgery. *Id*. at 23.

Petitioner was diagnosed with suspected TM given her incomplete paraplegia with numbness from umbilicus down, hyperintense signal at T10, and severe cervical stenosis with cord compression. Pet. Ex. 1 at 6. After no improvement of weakness after five days of IV steroids, plasma exchange was started. HIV testing was negative, cerebral spinal fluid had elevated proteins, and IgG was normal. *Id.* Neurosurgery recommended vertebrectomy, but she refused surgery after speaking with multiple providers because she would need to wear a collar and was claustrophobic: "[s]he understood the risk of not getting surgery and was willing to take this risk." *Id.* She was given a Prevnar vaccine. *Id*. at 7.

Without minimizing the debility petitioner suffered thereafter, an in-depth recitation of the extensive medical treatment she required is not necessary for purposes of this decision.[12] *See generally* Pet. Ex. 4A at 28; Pet. Ex. 4B at 177.

Petitioner received flu vaccines on October 29, 2014 and September 1, 2015. Pet. Ex. 4C at 232.

[11] TM usually develops over a few hours to a few days and may sometimes progress over several weeks. It usually affects both sides of the body below the affected area of the spinal cord, though it can affect just one side of the body. Typical signs and symptoms include: pain that may begin suddenly in the lower back with sharp pain that shoots down the legs or arms or around the chest or abdomen, numbness, tingling, coldness or burning, sensitivity to light touch or extreme hot or cold, or a feeling as though there is something tightly wrapped around the skin; weakness in arms or legs, stumbling, foot dragging or heaviness in the legs, severe weakness or total paralysis; and may include bladder and bowel problems. Resp. Ex. C.

[12] Petitioner was cared for in her home after refusing to go to a nursing home, which would have required her to sell her house to be eligible for additional services through Medicaid. Pet. Ex. 4 at 40-41.

B. Petitioner's Affidavits

Petitioner submitted two affidavits. Pet. Ex. 5; Pet. Ex 8. The first affidavit was submitted twice, initially annexed to the petition and then refiled as Pet. Ex. 5.

In her first affidavit signed on September 9, 2016, petitioner affirmed that following receipt of her flu vaccine on September 13, 2013, and "sometime over the next couple of months I began to recognize some unusual symptoms that I had not experienced before in my life. While I did have a bad left knee, I was beginning to have pain in both my legs, entirely different than the knee difficulty I have had in the past." Pet. Ex. 5 at 1. She added, "[i]n the winter months, perhaps December, I began to experience a real weakness in both my legs and I can remember shoveling snow one day in pain and weakness, which caused me concern, as I had never experienced that before." *Id*. "[I]n December my legs felt weak and the muscles in my right leg felt like they were burning and that continued for many months leading up to hospitalization in May 2014." *Id*.

Petitioner recalled her feet and legs hurting "tremendously" while walking in the mall over Christmas in 2013 and fearing she would be unable to get back to her car; cleaning the kitchen in January 2014 and preparing to paint when she had to sit due to weakness, shaking, and "some kind of spasm"; this occurred again in February with burning of the right leg muscle; and feeling pain in her right leg every day at work and having to rub it from winter through spring 2014. Pet. Ex. 5 at 1-2. However, she affirmed that "it did not interfere significantly with my daily activities, so I did not think much about it." *Id*.

According to petitioner on May 8, 2014, she felt alright when she awoke, but her legs felt worse later that morning and she had to sit on the floor to avoid falling. Pet. Ex. 5 at 2. In the months that followed May 8, 2014, her condition worsened but "[n]one of the doctors told me precisely why that had happened…possibly an autoimmune reaction…but nobody gave any specific explanation as to what caused this paralyzing condition." *Id*.

Petitioner submitted a second affidavit on January 3, 2017, in which she detailed conversations she had with her prior attorney, James Blumenstiel, about concerns raised during the status conferences held in her case, the lack of any mention of her legs bothering her in her medical records until she presented to the ER on May 8, 2014, and how this could be "a basis upon which the Court could justifiably dismiss the case." Pet. Ex. 8 at 1. She affirmed that Attorney Blumenstiel came to her home on December 19, 2016 to discuss her medical records. *Id*.

Petitioner then affirmed that her focus in the eight months following her flu vaccine was "100% on the cancerous conditions for which I was undergoing treatment and checkups." Pet. Ex. 8 at 1-2.[13]

Petitioner then affirmed that "within two months of my flu vaccination on September 13, 2013, I began to experience aches and stiffness in both of my legs…[i]t was of little consequence to me…it did not represent near the threat to my life that my breast cancer and colon cancerous

[13] Petitioner had routine follow up medical appointments and testing but was not undergoing any treatment at that time. Treatment for her cancer had competed by February 8, 2013 and she was noted as stable at that time. Pet. Ex. 2 at 109.

condition presented…it was not a concern of mine at the time, it was just an inconvenience." Pet. Ex. 8 at 2.[14] Petitioner further affirmed that she had left knee pain for years, but her right knee pain after the flu vaccine was new. She did not think much of it, and it never occurred to her to mention her bilateral leg pain to her oncologists. *Id.* She added that it was never bad enough to interfere with work or her daily activities though she did have to stop shoveling in December because her legs bothered her. *Id.* She added that there was an incident in the fall while doing repairs in her kitchen, but her legs were too sore to continue. *Id.*[15]

Petitioner addressed the ER record from May 8, 2014, quoting the entry that "[S]he usually gets up and the stiffness resolves, but today her stiffness persisted…" as proof that she advised the doctors of problems with her legs prior to May 8, 2014. Pet. Ex. 8 at 3; Pet. Ex. 1 at 32.[16] She added that she did not make a big deal of it because she was "focused on my two forms of cancer and on 5/8/14, the sudden worsening of my legs." Pet. Ex. 8 at 3.

Petitioner affirmed that it was not until 2016 that she started reading about transverse myelitis and learned it could be secondary to vaccination. Shortly before the statute was about to run, she retained James Blumenstiel to file a petition on her behalf. Pet. Ex. 8 at 4. Petitioner also affirmed receiving a flu vaccine every year after the subject 2013 flu vaccine. *Id.*

III. Expert Reports

A. Treating Physician's Report/Opinion Letter of Dr. Yasushi Kisanuki, M.D.

Dr. Kisanuki issued a letter that was filed on September 19, 2017. The letter appears to be responding to questions asked of him by petitioner's attorney. Pet. Ex. 21.

Dr. Kisanuki wrote that he was following petitioner for complications related to her "**idiopathic transverse myelitis**; mainly for management of her muscle stiffness/spasms and pain."[17]

It appears Dr. Kisanuki was questioned about "**Guillain-Barre syndrome (GBS) in relationship to her preceding vaccine administration,"** to which he responded that petitioner "**does NOT have such neurologic conditions**" and the question is therefore "**not even clinically relevant"**. Pet. Ex. 21 at 1. Transverse myelitis is a spinal cord disorder while GBS is a peripheral nerve disorder, and "[t]here is NO clinical evidence that she had suffered from GBS, to the best of my knowledge." *Id.*

[14] Petitioner was no longer being treated for her breast cancer and the polyps found during a colonoscopy in October 2013 were benign with some cellular changes. No treatment was provided; a follow-up colonoscopy was scheduled for the following year in October 2014.

[15] It is unclear if this is the same incident mentioned in her first affidavit as occurring in February 2014 or if this was a different incident closer in time to the subject flu vaccine.

[16] Signs and symptoms of transverse myelitis include sudden onset of pain in the lower back shooting into arms, legs or around the chest and abdomen; abnormal sensations such as numbness, tingling, coldness or burning; weakness in the arms and legs and bladder and bowel problems. Resp. Ex. C. Stiffness is not a symptom of TM. Resp. Ex. G at 3.

[17] The boldfaced portions throughout this section are those that Dr. Kisanuki wrote in bold in his report.

According to Dr. Kisanuki, petitioner suffered from idiopathic transverse myelitis and "we **did NOT identify specific etiology** to explain her onset…" Pet. Ex. 21 at 1. Dr. Kisanuki described TM and the complications associated with it, many of which petitioner suffered. *Id*.

Dr. Kisanuki conceded that he lacked sufficient expertise to comment on the relationship between petitioner's "vaccine administration over the onset of her transverse myelitis, nor even cancer." Pet. Ex. 21 at 1. He therefore declined to comment on the "paperwork" provided by counsel and concluded that "[t]here is **NO established test to confirm such causality to the best of my knowledge."** *Id*.

Respondent filed Dr. Kisanuki's profile from The Ohio State University, Wexner Medical Center as Resp. Ex. F. ECF No. 46.

B. Treating Physician/Expert Report of Dr. Michael Racke, M.D.

Petitioner filed Dr. Racke's report on September 19, 2017. Like Dr. Kisanuki, Dr. Racke's report appears to respond to questions posed by counsel. The report included a summary of petitioner's medical history, receipt of a flu vaccine on September 13, 2013, and development of TM on May 8, 2014. Pet. Ex. 22 at 1.

Dr. Racke explained that the proposed theory for how infection or vaccination may be associated with TM involves an immune response that cross reacts with self-tissue, in this case nervous system myelin, that results in the patient developing TM. *Id.* at 1-2. The immune response is rapid and occurs in days to weeks. Pet. Ex. 22 at 1. Dr. Racke submitted that the best data "trying to address an association" between TM after vaccination was noted in a paper published in 2016 in the Journal of Clinical and Infectious Disease.[18] Pet. Ex. 22 at 1. That study used an exposure window of 5-28 days prior to the clinical event to determine whether vaccination had a significant effect on TM. After analyzing almost 64 million cases, the conclusion was that there was no association between prior immunization and TM. *Id*.

Dr. Racke concluded that the September 13, 2013 flu vaccination was not a major contributing factor, and though patients may have suffered from systemic signs after vaccination of stiffness and soreness, it is unlikely those symptoms reported in October 2013 progressed to TM in May 2014. Pet. Ex. 22 at 1.

Dr. Racke noted his credentials as a neurologist and expert in neuroimmunological disorders doing research and studying the immunopathogenesis of multiple sclerosis (MS), experimental autoimmune encephalomyelitis (EAE), and other demyelinating disorders such as TM. Pet. Ex. 22 at 2. He has authored over 200 articles on MS and EAE and has been funded by the National Multiple Sclerosis Society and the NIH for over 20 years. *Id*. He cautioned counsel that "…the major problem you face in Ms. Christner's case regarding causality is the time period after vaccination and the clinical event is really quite prolonged for a causal association." *Id.* Immune response between vaccination and onset of clinical event is 5-28 days. *Id*. at 2. Further, "[T]ransverse myelitis does not come on slowly, particularly such a severe case like Ms.

[18] Respondent filed this paper as Exhibit A. Roger Baxter et al., *Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis*, 63 CLINICAL INFECTIOUS DISEASES 1456-62 (2016).

Christner's case. It is unlikely that she had transverse myelitis at the time of the colonoscopy in October, 2013." Pet. Ex. 22 at 1.[19] He cautioned petitioner's counsel that the government could obtain experts who will come to similar conclusions that he did. *Id*. at 2.

Respondent filed Dr. Racke's profile from The Ohio State University, Wexner Medical Center as Resp. Ex. D and a list of Dr. Racke's publications as Resp. Ex. E. ECF No. 46.

C. Expert Report of Dr. Michael Miller, M.D.

Dr. Miller is board certified in pediatric rheumatology and board eligible by training in allergy and immunology. He is an "expert in medical record standards, serving as chairman of [a] hospital's Medical Records Committee . . . [and] project manager for [the] hospital's implementation of compliance with HIPAA regulations" and an "expert in the validity of patient reported symptoms, both in medical records and in affidavits…" Pet. Ex. 23 at 4-5.

Dr. Miller discussed the Health Insurance Portability and Accountability Act ("HIPAA") passed by Congress recognizing the failure of patients to realize the relevance of multiple symptoms when presenting to a physician. Pet. Ex. 23 at 2.

> Because of this, HIPAA permits patients to request and enter additions to their medical records, regarding symptoms . . . there are no time limits to patient entered additions to the medical record. Therefore, the absence of neuromuscular symptoms recorded by the patient's treating physician in visits after the flu vaccine was given are not a factor in determining that the only possible diagnosis was post-influenza vaccine transverse myelitis—given the contents of the patient's affidavit.

Pet. Ex. 23 at 2.

Based on his experience as the project manager of this hospital's compliance with HIPAA and being the Chairman of the Medical Records Committee, Dr. Miller opined that petitioner "gave an affidavit on September 9, 2016. The contents of this affidavit are equivalent to entry into the medical record…" Pet. Ex. 23 at 2; Pet. Ex. 5. In her affidavit petitioner affirmed that over the months following the September 2013 flu vaccine she experienced bilateral lower extremity pain followed by bilateral leg weakness and myalgia varying in intensity that began in December 2013 and persisted until her admission to the hospital for severe weakness on May 8, 2014. *Id*. The contents of this affidavit "must be considered in evaluating the cause of the patient's demyelinating disease." Pet. Ex. 23 at 3.

According to Dr. Miller inflammatory diseases including post-vaccination inflammatory demyelinating disease of the central nervous system ("CNS") are characterized by lymphocyte activation followed by scar tissue. Pet. Ex. 23 at 3. Numerous clinical studies show that in TM resulting from influenza vaccine some molecules on the surface of the inactivated virus in the vaccine are recognized by some lymphocytes bearing receptors, and when these lymphocytes become activated and travel to the spinal cord, they attach to nerve cells bearing molecules

[19] It appears the questions asked of Dr. Racke by counsel included an onset of symptoms in October 2013, since Dr. Racke mentions October 2013 in several contexts in his letter.

resembling those of the virus. *Id.* at 3-4. The lymphocytes release cytokines that cause swelling of the spinal cord and the deposition of scar tissue in the spinal cord. *Id*. at 4. Though rare, medical literature supports that some people "harbor such abnormal lymphocytes", but there is currently no way to identify these patients. *Id*. Dr. Miller did not provide a medically acceptable timeframe for the onset of TM following flu vaccination other than to reference onset as December of 2013 from petitioner's affidavit.

Dr. Miller relied on the package insert for the influenza vaccine, which includes TM as an adverse reaction, several case studies in which TM was reported after vaccination and four patients he has seen with severe, life-threatening, post-influenza vaccine inflammatory demyelinating disease of the CNS, including a patient rendered quadriplegic by TM. Pet. Ex. 23 at 4. Petitioner did not file the package insert or any of the literature Dr. Miller cited.

Dr. Miller concluded that when petitioner's affidavit is considered, the administration of the vaccine and onset of symptoms reported therein support a post-influenza vaccine transverse myelitis. All other possible causes of demyelinating disease were ruled out during petitioner's hospitalization. Pet. Ex. 23 at 3.

Respondent filed Dr. Miller's faculty profile and biography as Resp. Ex. B. ECF No. 46.

D. Expert Report of Dr. Jeffrey Cohen, M.D.

Respondent submitted the expert report of Dr. Cohen. Resp. Ex. G. Dr. Cohen has 38 years of experience in clinical neurology and teaching and is board certified in neurology, clinical neurophysiology, and neuromuscular medicine. He is a professor of clinical neurology at Dartmouth-Hitchcock Medical Center and The Geisel School of Medicine. He diagnoses, treats, and follows patients with TM as both inpatients and outpatients. Resp. Ex. G at 1.

Dr. Cohen described TM as an acute illness which evolves over a period of days to weeks but does not have a chronic presentation over an 8-month period. Symptoms of TM include significant weakness, bowel and bladder incontinence, and severe sensory loss. These were the symptoms petitioner presented with and reported starting on May 8, 2014. Her symptoms then evolved over the following weeks. Resp. Ex. G at 2-3.

Dr. Cohen reviewed the case studies Dr. Miller presented in his report to show the period for onset between vaccination and TM was at most four weeks. Resp. Ex. G at 3. Specifically, *Larner*[20] had onset within a few days of flu vaccine in an inmmunosuppressed individual. *Gui*[21] had a five-day onset of symptoms after influenza vaccine. *Bakshi*[22] had a four-week onset after vaccination with complete recovery. Dr. Cohen also listed several other case reports[23] of TM

[20] A. J. Larner & S. F. Farmer, *Myelopathy following influenza vaccination in inflammatory CNS disorder treated with chronic immunosuppression*, 7 EUR. J. NEUROLOGY 731-33 (2000). This article was not filed.
[21] Li Gui et al., *Acute transverse myelitis following vaccination against H1N1 influenza: a case report*, 4 INT'L J. CLINICAL & EXPERIMENTAL PATHOLOGY 312-14 (2011). This article was not filed.
[22] R. Bakshi & J. Mazziotta, *Acute Transverse Myelitis After Influenza Vaccination: Magnetic Resonance Imaging Findings*, 6 J. NEUROLOGY 248-250 (1996). This article was not filed.
[23] These articles were not filed, and Dr. Cohen provided only the titles. *See* Resp. Ex. G at 3-4.

occurring within two weeks of vaccination, but none included flu vaccine: *Rees* had a five-day onset after MMR vaccine. *Lim* had a 16-day onset after measles and rubella vaccines. *Holt* studied two individuals with onset of 2 weeks and 4 days, respectively, after rubella vaccines. *Tartaglion* had onset 2 weeks after Hepatitis B vaccine. *LaRovere* had a post-varicella infection with acute TM in a child previously vaccinated for varicella. No timeframe was noted. *Id*. at 3-4.

Dr. Cohen added that large epidemiological studies specifically looking for TM following vaccination found no association. *Nordin*[24] surveyed 75,906 pregnant women after influenza vaccine with no increased risk of adverse events. *Agmon-Levin*[25] conducted a study between 1970 and 2009 with one case of TM nine days after influenza vaccine, and *Baxter*[26] identified seven cases of TM within 5-28 days in 64,000,000 vaccines. Resp. Ex. G at 4.

Dr. Cohen documented petitioner's complaint of stiffness prior to May 8, 2014, noting that stiffness is not a symptom of TM. He added that her other complaints were nonspecific, and in retrospect could easily be explained by her severe cervical myelopathy or other nerve or muscle disorders. Resp. Ex. G at 3.

Dr. Cohen addressed Dr. Miller's opinions on HIPAA and the right to amend records, noting that the symptoms petitioner complained of in her affidavits do not prove a vaccine related TM because TM is an acute illness, not a chronic disorder that develops over time. Resp. Ex. G at 3.

Dr. Cohen concluded that petitioner's medical records do not document any symptoms associated with TM between September 13, 2013 and the onset of her TM on May 8, 2014. Her affidavit contained nonspecific symptoms that could have been from a number of her existing conditions, most likely her severe cervical stenosis and "the timeline connecting [petitioner's] influenza vaccine and the diagnosis of her TM is not clinically possible. None of [her] treating physicians including neurologists made an association between the influenza vaccine and [petitioner's] TM." Resp. Ex. G at 2, 4. The case reports cited by Dr. Miller are not applicable to this case. *Id*.

IV. Parties' Arguments

A. Petitioner's Motion

Petitioner argues that an analysis of the totality of circumstances associated with her petition demonstrates it was filed in good faith and with a reasonable basis. Motion for Fees at 3, ECF No. 95.

[24] James D. Nordin et al., *Maternal Safety of Trivalent Inactivated Influenza Vaccine in Pregnant Women*, 121 OBSTETRICS & GYNECOLOGY 519-25 (2013), filed as "Resp. Ex. N."
[25] N. Agmon-Levin et al., *Transverse myelitis and vaccines: a multi-analysis*, 18 LUPUS 1198-1204 (2009), filed as "Resp. Ex. I."
[26] Roger Baxter et al., *Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis*, 63 CLINICAL INFECTIOUS DISEASES 1456-1462 (2016), filed as "Resp. Ex. A."

The facts contained in her moving papers include that she suffered the onset of "paraplegic symptoms within days of receipt of her September 13, 2013 flu vaccine" and had multiple consultations with Drs. Racke and Kisanuki regarding the pain, numbness, and weakness she was experiencing after her receipt of the flu vaccine. Motion for Fees at 4; Pet. Ex. 5. She continued to experience significant pain, weakness, numbness, and limited range of motion in her limbs and was eventually diagnosed with TM believed to be caused by the influenza vaccine received in September 2013.[27] *Id*.

Petitioner argues that she has satisfied *Althen* Prong I, submitting that her "medical records discussing the fact that her transverse myelitis was an autoimmune reaction corresponds with an adverse reaction to the flu vaccine." Motion for Fees at 4. She cites to locations in the record where the words "inflammation of the spinal cord", "immunology" and/or "autoimmune reaction" were used. *Id.* She quotes Dr. Kisanuki's description of her condition. Pet. Ex. 21 at 1. She references Dr. Racke's discussion of case reports involving TM following various vaccinations and his statement that "[t]he theory between any infection or vaccination is that the immune response somehow cross reacts with self-tissue, this case nervous system myelin that results in the patient developing transverse myelitis." Motions for Fees at 5; Pet. Ex. 22.[28] She references Dr. Miller's medical theory connecting the flu vaccine to petitioner's symptoms by explaining how post-vaccination inflammatory demyelinating disease can result from influenza vaccine when surface molecules of the inactivated virus in the vaccine are recognized by lymphocytes bearing receptors that are activated and travel to the spinal cord, where they attach to nerve cells bearing molecules resembling those of the virus. These lymphocytes release molecules called cytokines that cause swelling of then scar tissue in the spinal cord. Motion for Fees at 5; Pet. Ex. 23 at 3-4. Thus, petitioner provided "the medical theory of how a vaccine caused nerve damage in petitioner" and satisfied *Althen* Prong I. Motions for Fees at 5.

As to *Althen* Prong II, petitioner argues that a logical sequence of cause and effect exists between the flu vaccine and petitioner's TM because she never had problems with her legs before the September 13, 2013 vaccine and her leg problems "only surfaced after the vaccination at issue". Motion for Fees at 6. Petitioner relies on the May 8, 2014 medical record that documents stiffness that usually resolves but did not resolve on that date as proof that she suffered from symptoms prior to the morning of May 8, 2014. She argues that her medical providers could not exclude neurological autoimmunity, stating "[S]ome of the medical providers…provided their opinions regarding the connection of the vaccine to petitioner's transverse myelitis. None could exclude the possibility that the transverse myelitis was caused by her vaccination." Motion for Fees at 6 (citing Pet. Ex. 1 at 22; Pet. Ex. 2 at 60). She quotes Dr. Racke claiming that he "acknowledged…there are case reports of transverse myelitis occurring after various vaccinations…" *Id.* (citing Pet. Ex. 22 at 1). Although conceding that Dr. Racke did not believe the vaccine played a major role in her TM, petitioner argues that Dr. Racke did not completely rule it out. Motion for Fees at 6. Finally, petitioner relied on Dr. Miller's opinion that based on the date of the vaccine and the onset of her symptoms, "the only possible diagnosis that, is consistent with the patient's course is a post-influenza vaccine adverse event…" and the package insert for flu vaccine lists TM as a neurological side effect. Motion for Fees at 6 (citing Pet. Ex. 23 at 2).

[27] The facts as contained in this paragraph are unsupported by any medical record or other evidence filed in this case.
[28] The quoted passages are taken out of context, do not represent the complete statements made by the physicians in their reports, and are made to appear as though they apply to this petitioner and causation in this case.

To satisfy Prong III of *Althen*, petitioner relied on her own affidavits and the May 8, 2014 medical record documenting "stiffness" which "usually resolves," but did not, followed by bilateral pain and weakness as proof that the onset of TM symptoms was prior to May 8, 2014. Motion for Fees at 7-8.

In addition to satisfying the three *Althen* prongs, petitioner argues that the following is "strong evidence demonstrating good faith and reasonable basis petitioner had at all times for pursuing this claims": respondent failed to produce evidence to combat petitioner's claim; the Court denied respondent's Motion for Summary Judgment; an onset hearing was discussed at one point which "demonstrate[d] there was a material issue of disputed fact regarding the onset of petitioner's symptoms in this case"; and the only reason the petition was dismissed was because petitioner passed away and the administrator of the estate decided not to pursue the claim. Motion for Fees at 8.

Petitioner concluded that the foregoing makes it clear petitioner had good faith and a reasonable basis for pursuing her claim and should be awarded fees and costs. Motion for Fees at 8.

B. Respondent's Response

Respondent maintained that petitioner failed to establish reasonable basis for her claim, is not entitled to an award of fees and costs, and the Motion for Fees and Costs should be denied. Response at 1, ECF No. 101.

Respondent incorporated by reference the medical and procedural history set forth in his Rule 4(c) Report. In his response to the Motion for fees, he added that petitioner's claim is cause-in-fact based on her allegation of "pain, weakness and limitations in her legs" with paraplegia following a September 13, 2013 flu vaccine. Response at 2; Petition at 2. Petitioner's counsel did not start compiling exhibits until the day the petition was filed, September 12, 2016. *See* Pet. Ex. 25 at 1. Petitioner's Exhibits 1-5 were filed on November 2, 2016, following petitioner's counsel's review of the records on the same date. However, the bottom of Exhibit 1 shows that the record was printed by the medical provider on July 27, 2016, before the petition was filed. Response at 2.

Respondent highlighted portions of petitioner's medical records documenting her sudden onset of symptoms of TM as May 8, 2014. Also highlighted were the medical records of petitioner's treating physicians Drs. Racke and Kisanuki's documenting petitioner's onset of symptoms of TM as May 8, 2014. Both issued letters unsupportive of vaccine causation. Dr. Racke specifically opined that the flu vaccine was not the likely cause of petitioner's TM. Response at 2; Pet. Ex. 4B at 115, 133.

Respondent agrees that petitioner received a flu vaccine on September 13, 2013 and suffered TM that began on May 8, 2014, eight months after the subject flu vaccine. Response at 3. Respondent addressed petitioner's affidavits affirming onset of TM "in the winter months, perhaps December" or "over the next couple of months" after vaccination. He noted that petitioner presented for medical care on at least seven occasions between September 13, 2013 and May 8,

2014 with no mention of any complaints or symptoms associated with TM. Response at 3 (citing Pet. Ex. 5 at 1; Pet. Ex. 8 at 3; Pet. Ex. 4 at 61-62, 156-57; Pet. Ex. 3 at 109, 129; Pet. Ex. 11 at 13, 18).

Respondent pointed out that the eight-month gap between vaccination and the onset of petitioner's TM were discussed during the initial conference on December 8, 2016, when petitioner's counsel advised that he was contacted on the eve of the statute and was still gathering records. Response at 3-4; ECF No. 9 at 1. Counsel then filed Exhibits 6-7 on December 19, 2016; Exhibits 9-12 on March 3, 2017; Exhibits 13-19 on March 9, 2017 and Exhibit 20 on May 18, 2017. No further records were filed. Response at 4. Petitioner also filed three expert reports on September 19, 2017. ECF Nos. 39-40. Those expert reports reflect that Dr. Kisanuki did not identify a specific etiology for petitioner's TM. Response at 4; Pet. Ex. 21 at 1. Dr. Racke opined that the vaccine was not a contributing factor to the onset of the TM; it was unlikely that the symptoms reported in her affidavit as October 2013 progressed to TM in May 2014; immune response after vaccination is rapid, occurring in days to weeks; and a 5–28-day window after vaccination is used for association between vaccination and TM. Dr. Racke concluded that the foregoing was raised because the government can easily obtain experts that will come to the same conclusions he reached. Response at 4.

Respondent addressed Dr. Miller's opinions, noting that Dr. Miller is pediatric rheumatologist not qualified to opine on immunology. Dr. Miller ignored the medical history contained in the contemporaneous medical records, based his opinions on her affidavits, argued that HIPAA permits her to change her records, and concluded that her injuries were casually related to her flu vaccine. Response at 5. Dr. Miller's report did not comply with the *Althen* criteria and no objective evidence was provided to support petitioner's claim for purposes of satisfying reasonable basis. *Id*. Respondent quoted from his Rule 4 (c) Report filed on October 4, 2017, which specifically stated that "the expert reports filed by petitioner make it abundantly clear that this petition lacks a reasonable basis". Response at 5; Resp. Rpt. at 13.

Respondent relied on the report of Dr. Jeffrey Cohen and the procedural history contained in the Court's decision dismissing this case for insufficient proof for the remainder of the events. Response at 5; Resp. Ex. G; ECF No. 91 at 3-5.

Respondent then addressed petitioner's Motion for Attorneys' Fees and Costs, highlighting several statements contained therein that were misleading and/or unsupported by the record including: petitioner experienced paraplegic symptoms within days of her September 13, 2013 flu vaccine; petitioner consulted with Drs. Kisanuki and Racke regarding the pain, numbness, and weakness she was experiencing after receiving her vaccination; her subsequent diagnosis of TM that was "believed to have been caused by the influenza vaccine she received in September of 2013"; the temporal relationship between her vaccine and TM was supported by the May 8, 2014 record, this record was proof that her symptoms began prior to May 8, 2014; and the reason the case was dismissed was because petitioner passed away and the administrator decided not to pursue the claim further. Response at 11-12; Motion for Fees at 4, 7, 8.

Respondent concluded that the objective evidence in this case supports the onset of TM eight months after vaccination, "which is not medically appropriate for the flu vaccine to have

been a viable cause for [petitioner's] TM." Response at 12. None of petitioner's treating physicians related the vaccine to her TM, and two of them wrote reports to that effect. *Id*. Dr. Miller, petitioner's third expert and a rheumatologist, opined in this case on a medical condition outside of his specialty and based his opinions on facts in affidavits that were unsupported by the contemporaneous medical records. *Id*. Therefore, petitioner's claim lacked reasonable basis when filed and reasonable basis was never established. Consequently, no fees or costs should be awarded. *Id*. at 13.

C. Petitioner's Reply

Petitioner filed a reply arguing that her focus in the months following her flu vaccine was her potential cancer, not her vaccine-related symptoms. Reply at 1, ECF No. 102. Her affidavits linked her symptoms to the administration of the vaccination, sufficiently satisfying reasonable basis under *James-Cornelius*. *Id*. Dr. Miller opined that the only possible diagnosis consistent with petitioner's course is post-influenza vaccine adverse reaction and Dr. Racke "could not refute the vaccine could be a contributing cause to petitioner's condition." *Id*. at 2; Pet. Ex. 23 at 2. The package insert for the flu vaccine shows TM as a neurological side effect of the influenza vaccine, demonstrating the reasonableness of the claim under *Cottingham.* Reply at 2; Pet. Ex. 23 at 4. Finally, the "Court ordered a fact hearing in this case" which demonstrates that a reasonable basis existed for the case; respondent failed to produce evidence adequately combating petitioner's evidence and petitioner successfully fought off a Motion for Summary Judgment, demonstrating a material issue of fact such that reasonable basis existed for filing and pursuing this case. Therefore, the Motion for Attorneys' Fees and Costs should be granted. Reply at 2.

V. Legal Standard

A. Good Faith

"Good faith" is a subjective standard. *Hamrick v. Sec'y of Health & Human Servs.*, No. 99-683V, 2007 WL 4793152, at *3 (Fed. Cl. Spec. Mstr. Nov. 19, 2007). A petitioner acts in "good faith" if he or she holds an honest belief that a vaccine injury occurred. *Turner v. Sec'y of Health & Human Servs.*, No. 99-544V, 2007 WL 4410030, at *5 (Fed. Cl. Spec. Mstr. Nov. 30, 2007). Without evidence of bad faith, "petitioners are entitled to a presumption of good faith." *Grice v. Sec'y of Health & Human Servs.*, 36 Fed. Cl. 114, 121 (1996). Thus, so long as petitioner had an honest belief that her claim could succeed, the good faith requirement is satisfied. *See Riley v. Sec'y of Health & Human Servs.*, No. 09-276V, 2011 WL 2036976, at *2 (Fed. Cl. Spec. Mstr. Apr. 29, 2011) (citing *Di Roma*, 1993 WL 496981, at *1); *Turner*, 2007 WL 4410030, at *5.

Since good faith was not raised by respondent, it will not be addressed, and petitioner is afforded the presumption of good faith in the filing of this petition.

B. Reasonable Basis

Reasonable basis, however, is an objective inquiry, irrespective of counsel's conduct or a looming statute of limitations, that evaluates the sufficiency of records available at the time a claim is filed. *Simmons v. Sec'y of Health & Human Servs.*, 875 F.3d 632, 636 (Fed. Cir. 2017); *see*

Turpin v. Sec'y of Health & Human Servs., No. 99-564, 2005 WL 1026714 at *2 (Fed. Cl. Spec. Mstr. Feb. 10, 2005). When determining if a reasonable basis exists, special masters and judges consider a myriad of factors. The factors to be considered may include "the factual basis of the claim, the medical and scientific support for the claim, the novelty of the vaccine, and the novelty of the theory of causation." *Amankwaa v. Sec'y of Health & Human Servs.*, 138 Fed. Cl. 282, 289 (2018). The Federal Circuit concluded that "counsel may not use [an] impending statute of limitations deadline to establish a reasonable basis for [appellant's] claim." *Simmons*, 875 F.3d at 636. Further, an impending statute of limitations should not even be one of several factors the special master considers in her reasonable basis analysis. "[T]he Federal Circuit forbade, altogether, the consideration of statutory limitations deadlines—and all conduct of counsel—in determining whether there was a reasonable basis for a claim." *Amankwaa*, 138 Fed. Cl. at 289.

Reasonable basis is satisfied when there is a mere scintilla of objective evidence, such as medical records or medical opinions, supporting a feasible claim before filing. *See Cottingham ex. rel. K.C. v. Sec'y of Health & Human Servs.*, 971 F.3d 1337, 1346 (Fed. Cir. 2020); s*ee Chuisano v. Sec'y of Health & Human Servs.*, 116 Fed. Cl. 276, 286 (2014) (citing *McKellar v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 303, 303 (2011)); *Silva v. Sec'y of Health & Human Servs*., 108 Fed. Cl. 401, 405 (2012). A recent attempt to clarify what quantifies a scintilla looked to the Fourth Circuit, which characterized "more than a mere scintilla of evidence" as "evidence beyond speculation that provides a sufficient basis for a reasonable inference of causation." *Cottingham v. Sec'y of Health & Human Servs.*, 154 Fed. Cl. 790, 795 (2021) (quoting *Sedar v. Reston Town Ctr. Prop., LLC*, 988 F.3d 756, 765 (4th Cir. 2021)). Additionally, absence of an express medical opinion of causation is not necessarily dispositive of whether a claim has a reasonable basis. Medical records may support causation even where the records provide only circumstantial evidence of causation. *James-Cornelius*, 984 F.3d at 1379-80.

In discussing the reasonable basis requirement in *Cottingham*, the Federal Circuit stressed the prima facie petition requirements of § 11(c)(1) of the Act. Specifically, the petition must be accompanied by an affidavit and supporting documentation showing that the vaccinee:

(1) received a vaccine listed on the Vaccine Injury Table;
(2) received the vaccination in the United States, or under certain stated circumstances outside of the United States;
(3) sustained (or had significantly aggravated) an injury set forth in the Vaccine Injury Table (42 C.F.R. § 100.3(e)) or that was caused by the vaccine;
(4) experienced the residual effects of the injury for more than six months, died, or required an in-patient hospitalization with surgical intervention; and
(5) has not previously collected an award or settlement of a civil action for damages for the same injury.

Cottingham, 971 F.3d at 1345-46.

Special masters cannot award compensation "based on the claims of petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a)(1). However, absence of an express medical opinion of causation is not necessarily dispositive of whether a claim has a reasonable basis. Medical records may support causation even where the records provide only

circumstantial evidence of causation. *James-Cornelius on Behalf of E. J. v. Sec'y of Health & Human Servs.*, 984 F.3d 1374, 1379-80 (Fed. Cir. 2021). While absent or incomplete records do not strictly prohibit a finding of reasonable basis, an overwhelming lack of objective evidence will not support reasonable basis. *Chuisano*, 116 Fed. Cl. at 288; *see Simmons*, 875 F.3d at 634-36 (holding that reasonable basis was not satisfied where 1) petitioner's medical record lacked proof of vaccination and diagnosis and 2) petitioner disappeared for two years before filing a claim). The objective evidence in the record must also not be so contrary that a feasible claim is not possible. *Cottingham*, 154 Fed. Cl. at 795, citing *Randall v. Sec'y of Health & Human Servs.*, No. 18-448V, 2020 WL 7491210, at *12 (Fed. Cl. Spec. Mstr. Nov. 24, 2020) (finding no reasonable basis when petitioner alleged a SIRVA injury in his left arm though the medical records indicated that the vaccine was administered in petitioner's right arm). A claim may lose reasonable basis as it progresses if further evidence is unsupportive of petitioner's claim. *See R.K. v. Sec'y of Health & Human Servs.*, 760 F. App'x 1010, 1012 (Fed. Cir. 2019) (citing *Perreira v. Sec'y of Health & Human Servs.*, 33 F.3d 1375, 1376–77 (Fed. Cir. 1994)).

VI. Discussion

A. Reasonable Basis

Petitioner's claim was that the flu vaccine she received on September 13, 2013 caused her to suffer "pain, weakness, and limitations in her legs" and paraplegia. *See* Petition. However, she was diagnosed with TM eight months after her flu vaccine, during a hospitalization in May 2014, years before filing her petition. Pet. Ex. 1 at 6. A thorough examination of petitioner's proffered evidence fails to demonstrate any objective evidence that a flu vaccine can cause TM eight months after vaccination; that TM can develop with mild symptoms that progress to an abrupt onset of severe symptoms over an eight-month period; or that petitioner suffered any symptoms associated with TM between the receipt of the flu vaccine on September 13, 2013 and her abrupt onset of symptoms on the morning of May 8, 2014.

1. Petitioner's Medical Records and Affidavit Do Not Establish Reasonable Basis

In her supplemental affidavit, petitioner affirmed that she began to research TM in early 2016 and learned of the association between TM and the flu vaccine. Pet. Ex. 8 at 4. She then contacted counsel, though the date of contact is not reflected in counsel's billing records, and met with then-counsel James Blumenstiel at her home on September 6, 2016. Pet. Ex. 25 at 1. Six days later and one day before the statute of limitations would run, the petition was filed on September 12, 2016. The petition alleged that petitioner suffered from "pain, weakness, and limitations in her legs" and paraplegia. Petition at ¶¶ 4, 5. Despite petitioner's diagnosis and treatment of TM in 2014, the petition did not allege TM as her injury. The petition was accompanied only by petitioner's affidavit, which placed onset "over the next couple of months" after the September 13, 2013 flu vaccination, or perhaps in December 2013, three months post-vaccination. Pet. Ex. 5 at 1.

Petitioner filed her medical records as Exhibits 1-5 on November 20, 2016. ECF No. 7. These medical records contained the information necessary to analyze petitioner's claim and included her diagnosis of TM. The medical records reflect that petitioner made no complaints to any medical professional of any symptoms or complaints associated with leg weakness, numbness,

pain, or her September 13, 2013 flu vaccine between September 13, 2013 and May 8, 2014, despite having attended approximately seven medical visits in that eight-month period. *See* Pet. Ex. 2-5. Petitioner's Exhibit 1 contained the May 8, 2014 emergency room visit at which petitioner reported the onset of symptoms characteristic of TM as beginning that morning. Pet. Ex. 1 at 3. Petitioner's symptoms continued to develop in the weeks following her May 8, 2014 presentation to the emergency room as her TM progressed. *Id*.; Resp. Ex. C. Thereafter, petitioner consistently reported to her medical providers at various facilities that she suffered an abrupt onset of bilateral weakness, numbness, and pain on May 8, 2014. *See* Pet. Ex. 1 at 3; Pet. Ex. 9 at 4; Pet. Ex. 10 at 8; Pet. Ex. 13 at 22.

Petitioner suffered from, was diagnosed with, and was treated for TM following her admission to the hospital on May 8, 2014, more than two years prior to her meeting with counsel on September 6, 2016 and the filing of the petition. Although petitioner's medical records were not filed until November 20, 2016, more than two months after the petition was filed, the medical record designated as Exhibit 1 reflects that it was printed in July 2016. *See* Pet. Ex. 1. Further, the petition did not allege that petitioner suffered from TM as the result of her September 13, 2013 flu vaccine, and the petition was never amended to reflect TM as the alleged injury even after the medical records documenting her diagnosis and treatment were filed.

In her second affidavit, petitioner documented her discussions with counsel about the issues raised at the status conference in December 2016, including the onset of her injury and the lack of any mention in her medical records of injuries associated with her September 2013 flu vaccine until her presentation to the ER on May 8, 2014. Petitioner also affirmed onset of symptoms now as "within a couple of months" of the September 13, 2013 vaccine. Pet. Ex. 8. She affirmed that she did not discuss her symptoms with any medical providers between September 13, 2013 and May 8, 2014 because she was seeing oncologists and was focused on her cancer treatment. *Id*. However, review of petitioner's medical records show that her cancer treatment was completed by February 8, 2013, and she was attending only routine follow-up appointments and testing between September 2013 and May 2014. Pet. Ex. 2 at 109; *see* Pet. Ex. 3. To that end, she had a colonoscopy with benign polyp removal in October 2013; the polyps were benign, but she stated they were "very near cancerous." Pet. Ex. 3 at 109; Pet. Ex. 8 at 1. No treatment was ordered other than a follow-up colonoscopy the following year. Pet. Ex. 3 at 109. She also underwent thyroid ultrasounds as she was being monitored for nodules, but no treatment was prescribed. Pet. Ex. 4A at 50, 62. Her explanation for why she did not mention any complaints associated with her alleged injuries following receipt of the flu vaccine and for eight months thereafter were unconvincing and unsupported by her medical records. Pet. Ex. 8; Pet. Ex. 2 at 109; *see* Pet. Ex. 3.

In her Reply to respondent's Response to her Motion for Attorneys' Fees and Costs, petitioner argues that her affidavits are sufficient to support reasonable basis for filing the petition, under *James-Cornelius*. Reply at 1.[29] She argues that she did not have any pain or weakness before her vaccine and facts that included "pain and weakness in both legs within a few weeks of the

[29] In the moving papers, petitioner's counsel failed to mention *Simmons* or *Cottingham*. *See* Motion for Fees. Thus, his excuse that he failed to timely file his application for fees and costs because he was researching reasonable basis in order to support his motion is questionable.

vaccine." *Id*.; Pet. Ex. 5 at ¶¶ 5, 8.[30] "By January 2014, she felt her legs might give out due to pain and weakness." Reply at 1-2.[31] By May 2014, her condition had progressed to the point she was a paraplegic and was diagnosed with transverse myelitis. Ex 1, 5, 8.[32] Petitioner argues that this evidence cannot be ignored, has never been refuted, and establishes a reasonable basis for filing and pursuing the claim. *Id*. at 2.

While affidavits "can be used to support reasonable basis," affidavits alone, without supporting documentation are not sufficient. Reply at 2. In *James-Cornelius*, the Federal Circuit stated that a petitioner's affidavit was evidence that can support a claim for causation. However, in that case, the Court specifically noted that the affidavit, when taken together with corroborating medical records and the package insert, "amount to relevant objective evidence supporting causation." *James-Cornelius*, 984 F.3d at 1381. In the instant matter, the "evidence" or facts that petitioner refers to in her Reply as establishing reasonable basis do not exist anywhere in the records filed in this matter. Petitioner does nothing more than cherry-pick words and phrases out of the medical records in an attempt to create the illusion of supportable evidence for reasonable basis. However, when the contemporaneous medical records are read in their entirety, the "evidence" is wholly uncorroborated.

Petitioner's reliance on the package insert is similarly inadequate. Even though *Cottingham* discusses vaccine package inserts, *Cottingham* did not involve an eight-month onset interval. The mention of TM along with other adverse events in the package insert is insufficient to establish reasonable basis without more. This is especially true when, as discussed further below, two of petitioner's treating physicians declined to associate her TM with the flu vaccine and medical literature does not support a progressive onset for TM over an eight-month period. *See* Pet. Ex. 21; Pet. Ex. 22; Resp. Ex. G. Thus, I decline to give the manufacturer's package insert more weight than the medical literature discussing TM and expert opinions filed herein.

This matter was ultimately dismissed for lack of sufficient proof not, as represented in petitioner's moving papers, because petitioner passed away. Motion for Fees at 8; Dismissal Decision, ECF No. 91. Aside from petitioner's affidavits, there is no corroborating evidence to support petitioner having suffered from any symptoms between her receipt of the flu vaccine on September 13, 2016 and the onset of TM on the morning of May 8, 2014. Further, there is no support for the onset of TM being progressive and prolonged over months as set forth below. Based on the records filed in this case, I find that petitioner's affidavit, without any objective evidence to support the claims made, cannot establish reasonable basis in support of her claim.

[30] "Within a few weeks" is not contained anywhere in petitioner's affidavits – she affirmed "sometime over the next several months", "in December", and "within a couple of months." Pet. Ex. 5; Pet. Ex. 8.

[31] This information is not contained in any record or affidavit filed in this case.

[32] This statement is unsupported by the record. On May 8, 2014 petitioner was diagnosed with suspected TM given incomplete paraplegia and numbness from the umbilicus down; hyperintense signal at T10 on MRI of the thoracic spine; and severe cervical stenosis with cord compression. Neurosurgery was recommended, but she refused because she was claustrophobic and would need to wear a collar. The record documented that she "understood the risk of not getting surgery and was willing to take this risk." Pet. Ex. 1 at 6. In the many months that followed, her condition progressed to paraplegia, with a need for colostomy and catheter due to urinary retention and other serious complications.

2. Petitioner's Physician Letters and Expert Report Do Not Establish Reasonable Basis.

Petitioner filed letters from two of her treating physicians, Dr. Kisanuki and Dr. Racke. Neither physician associated her September 13, 2013 flu vaccine with her TM. Pet. Ex. 21; Pet. Ex. 22. Dr. Racke, a neuroimmunologist, opined that TM does not come on slowly and it was unlikely that petitioner had TM in October 2013. Pet. Ex. 22 at 1. He added the body's immune response to vaccination is rapid, and when there is a cross reaction with self-tissue that results in the development of TM, it occurs within 5-28 days. *Id*. at 1-2. Respondent's expert Dr. Cohen described TM as an acute illness which evolves over days to weeks but does not have a chronic presentation over an eight-month period. Resp. Ex. G at 2-3. Symptoms of TM include significant weakness, burning, bowel and bladder incontinence, and sensory loss, the symptoms that petitioner began experiencing the morning of May 8, 2014 and which evolved in the weeks thereafter. *Id.* Dr. Cohen added that stiffness is not a symptom of TM but could have been a symptom of her other conditions, like her severe cervical myelopathy. *Id.* at 3.

Even if the facts recited in petitioner's affidavits were accepted as true, there is no support in the medical records, medical literature, or medical opinions in this case for the onset of TM or any demyelinating disease in excess of two months following influenza vaccine. *See, e.g., Farley v. Sec'y of Health & Human Servs.*, No. 13-683V, 2015 WL 5031989 (Fed. Cl. Spec. Mstr. July 31, 2015) (Special Master Gowen dismissed a petition where the onset of TM symptoms occurred three months after a flu vaccination); *Schmidt v. Sec'y of Dep't of Health & Human Servs*., No. 07-20V, 2009 WL 5196169 (Fed. Cl. Spec. Mstr. Dec. 17, 2009) (finding onset of TM one month after a flu vaccination medically appropriate). Further, based on the entitlement decisions related to TM issued prior to the filing of the instant petition, petitioner's counsel should have been aware that the alleged eight-month onset of TM was far beyond the period of onset for TM that has been accepted following any vaccination. *See Pecorella v. Sec'y of Dep't of Health & Human Servs.*, No. 04-1781V, 2008 WL 4447607 (Fed. Cl. Spec. Mstr. Sept. 17, 2008) (finding a two-month onset interval between Hepatitis B vaccination and TM was a medically appropriate timeframe); *Fockler v. Sec'y of Health & Human Servs.*, No. 13-237V, 2014 WL 1569192 (Fed. Cl. Spec. Mstr. Mar. 31, 2014) (finding a three-month onset interval of TM after Hepatitis B vaccination was "too long to connote causation").

In her Reply, petitioner argues that she provided the expert opinion of Dr. Miller, even though a supporting medical opinion is not required to establish reasonable basis under *James-Cornelius*. She argues that in Dr. Miller's opinion, the "only possible diagnosis that is consistent with the patient's course is a post-influenza vaccine adverse event. The patient's physicians (sic) excluded all other possible causes." Reply at 2; Pet. Ex. 23 at 2. She further argues that "Dr. Racke could not refute that the vaccine could be a contributing cause to petitioner's condition", and that Dr. Miller "correctly" highlighted the package insert, which includes TM as a rare neurologic "side effect" and petitioner had these symptoms "shortly after the vaccination." Reply at 2.

Petitioner's parroting of phrases contained in the case law and partial statements taken out of context from the medical records is unpersuasive. Additionally, Dr. Miller's opinions carry little weight since they are based exclusively on petitioner's affidavits, drafted three years after the events, with facts that are contrary to the contemporaneous medical records. Further, Dr. Miller

was uninformed about the onset of and symptoms associated with TM, and the medically appropriate timeframe within which TM develops following infection or vaccination. In support of his opinions, Dr. Miller relied on two case studies associating flu vaccine with TM, while disregarding that onset occurred within 2-4 weeks of vaccination in both cases. A discussion of the general principles of immune response as a purported mechanism for injury does not satisfy the *Althen* criteria, and Dr. Miller did little more than that. Dr. Miller's opinion is contrary to what is known about TM and does not support reasonable basis for pursuing petitioner's claim.

Under the Act, a petitioner may not be given a Program award based solely on the petitioner's claims. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 13(a)(1). An expert's opinion does not necessarily provide reasonable basis for a claim. *See Perreira v. Sec'y of Dep't of Health & Human Servs.*, 33 F.3d 1375 (Fed. Cir. 1994) ("once petitioners-appellants reviewed the expert opinion upon which their case depended, they no longer had a reasonable basis for claiming causation in-fact because the expert opinion was grounded in neither medical literature nor studies"). Dr. Miller's expert opinion is contrary to what is known about TM and its onset, relies on only the facts provided by petitioner in her affidavits which are uncorroborated by the contemporaneous medical records, and is refuted by the opinions of petitioner's treating physicians and respondent's expert. Accordingly, petitioner's expert report was unsupportive in establishing reasonable basis for the claim.

3. The Denial of the Motion for Summary Judgment and Discussion of a Fact Hearing Do Not Establish Reasonable Basis.

Petitioner argues that reasonable basis exists because "the Court ordered a fact hearing for this case" and petitioner "also successfully fought off a motion for summary judgment." Reply at 2. Neither argument is persuasive.

Petitioner's argument that reasonable basis existed because the undersigned "ordered a fact hearing for this case" is of no significance in supporting reasonable basis. Reply at 2. At an unrecorded status conference on September 27, 2017, a fact hearing was discussed, but respondent requested a date to file his Rule 4(c) Report. The parties were asked to confer and provide a date for a fact hearing in a joint status report. ECF No. 42. However, two days later, on September 29, 2017, petitioner filed a "First Motion for Hearing on Entitlement", asking that the matter be set for hearing on entitlement sooner rather than later and suggesting that a "Staff Attorney or Magistrate" conduct the hearing in the event the Court's calendar did not permit an earlier hearing date. ECF No. 44 at 2. On October 4, 2017, respondent filed his Rule 4(c) Report detailing the evidence and concluding the claim lacked reasonable basis. ECF No. 46 at 13. Petitioner's September 29, 2017 filing for a "Hearing on Entitlement" reflected petitioner's belief that the record was complete, despite the ongoing issues raised during every status conference. When respondent filed his Rule 4(c) on October 4, 2017, petitioner was certainly aware that respondent raised reasonable basis in this matter based on the record and the reports of petitioner's own treating physicians. Discussions during a status conference about whether a fact hearing would be useful is not a confirmation by the Court that a case has reasonable basis and certainly is not in a case such as this where there was an eight-month gap between receipt of a flu vaccine and onset of injury, facts which were repeatedly discussed with petitioner's counsel since the first status conference held in this matter.

Additionally, respondent's Motion for Summary Judgment was denied because the Motion was procedurally flawed, not because petitioner's claim had reasonable basis. The Vaccine Rules do not authorize factfinding on summary judgment: "To allow a special master to weigh and find facts prior to the end of the case (effectively at an arbitrary point in the litigation dictated by the summary judgment movant) would raise serious due process concerns.'" *Jay v. Sec'y of Dep't of Health & Human Servs.*, 998 F.2d at 982-83. When the Motion for Summary Judgment was filed, the issue of onset needed to be resolved. I would have had to first determine *when* petitioner developed TM as between the competing medical records and petitioner's affidavits, which I was not authorized to do on summary judgment. ECF No. 63. The Motion was denied on procedural grounds and therefore, petitioner did not successfully fight off a Motion for Summary Judgment, nor did the denial confer reasonable basis to petitioner's claims.

VII. Conclusion

Having examined all the evidence in the record, I find that petitioner has failed to present even a scintilla of evidence connecting the flu vaccine received on September 13, 2013 to her TM that developed abruptly on the morning of May 8, 2014. Reasonable basis did not exist at the time of filing, nor was it gained at any point during the pendency of the case.

Based on the foregoing, petitioner's Motion for Attorneys' Fees and Costs is **DENIED**. The Clerk of Court is directed to enter judgment in accordance with this decision. [33]

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master

[33] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.